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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,475	07/27/2001	Brian D. Andresen	IL-10380	1094

7590

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EXAMINER
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ROGERS, DAVID A

ART UNIT	PAPER NUMBER
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2856

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/917,475	<b>Applicant(s)</b> ANDRESEN ET AL.	
	<b>Examiner</b> David A. Rogers	<b>Art Unit</b> 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-15 and 17-35 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23, 25-30 and 33-35 is/are allowed.
- 6) ☒ Claim(s) 1,4-15,17,19 and 21 is/are rejected.
- 7) ☒ Claim(s) 18,20,22,24,31 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

1. The USPTO is in the process of moving to new office spaces in Alexandria, Virginia. Please note the new phone numbers for the examiner and the examiner's supervisor below.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 March 2004 has been entered.

3. Claims 1, 3, and 16 have been canceled. Claims 1, 4-15, and 17-35 remain pending in this application.

***Specification***

4. The disclosure is objected to because of the following informality. On page 2, §0007, line 5 replace --porosity-- with --porosity--. Appropriate correction is required.

***Claim Objections***

5. Claims 22 and 31 are objected to because of the following informality. The claims recite the use of extraction media having a "loose particulate composition." These claims should recite that, if an open end section is selected, then the open end must be sized smaller than the active extraction

media. This is similar to the requirement that the holes on the porous sheath be sized smaller than the active media. Appropriate correction is required.

***Double Patenting***

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

8. Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9. Claim 31 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 22. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Claim 32 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 24. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1 and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,693,228 to Koehler *et al.* in view of United States Patent 6,164,144 to Berg and United States Patent 6,042,787 to Pawliszyn.

Koehler teaches a device for solid phase microextraction (SPME) comprising fiber (reference item 46) in a protective metal sheath (reference item 57). The protective sheath and fiber are extracted to and from and retained in a needle (reference item 44) that further comprises a pointed tip for piercing a septum. Fiber 46 is a solid thread-like material that is extendable from the needle 44 through the barrel 50 and out end 56. The end of the fiber located adjacent to handle 53 has retention means (not shown) located thereon so that the fiber will move longitudinally as plunger 52 slides within the barrel. The fiber is partially enclosed within metal casing (sheath) which surrounds that portion of the fiber located within the plunger, barrel, and part of the needle. The purpose of the metal casing is to protect the fiber 46 from damage and to ensure a good seal during operation of the device. In general terms, the syringe is a typical housing for the fiber and the access means is the action of plunger in moving fiber beyond tip of needle.

The active coating on the fiber can be comprised of solid polymeric materials such as

polydimethylsiloxane (PDMS)	octadecyltrichlorosilane
polyacrylate	polymethylvinylchlorosilane
graphite	liquid crystalline polyacrylates
carbowax	grafted self-assembled monolayers
silicone	inorganic coatings
polyimide	

and combination of the aforementioned coatings. In the above list graphite is a well-known particulate material. Koehler *et al.* does not teach the use of a porous sheath comprising active media where the porous sheath is movably mounted in the needle.

Berg teaches a device to be used with SPME comprising a pointed, open-ended needle (reference item 24) connected to a syringe (reference item 10). The needle further comprises a stationary phase coating (reference item 32) along the inner surface (reference item 30) of the needle, as seen in Figure 1B. Berg further teaches an example of using the needle where the stationary phase coating is polydimethylsiloxane (column 6, lines 10-20), a material that the applicant discloses as active materials commonly used for SPME. In use the needle is both capable of piercing a septum (reference item 84), as seen in Figure 1, and forming a seal with the septum. Berg, however, does not disclose a needle formed with holes or perforations along its length.

It is well known that SPME results are optimized when the amount of sample that is exposed to the active media on the probe is increased. Methods to arrive at these optimized results include instilling motion to the sample, e.g. agitation, stirring, or mixing. See the teachings of Koehler *et al.* where a vibrating table is used to cause the fiber to oscillate in order to increase adsorption. Also, increasing the amount of circulation across the active media's boundaries can also be used. In either case, increasing the amount of sample that is exposed to the active media helps to reduce the extraction time

(see Berg, column 2, lines 36-40). A moving sample also helps to ensure that all of the possible analytes in the sample are exposed to the active media in order that they can be detected using devices such as gas chromatographs or mass spectrometers. It is also well known and understood in the art of sampling probes that sheaths are used to protect a sensitive member from damage due to exposure to moving media such as an agitated solution, or to other environmental concerns such as thermal shock. See again Koehler *et al.* where a sheath is used to protect the fiber. It is also very well known that such protective sheaths are provided with holes, perforations, or apertures in order to increase the amount of sample that the sensitive member is exposed to while also ensuring that the sensitive member is not damaged during use.

In this regard Pawliszyn teaches a SPME device comprising a member with an extraction coating (reference item 80) that is generally surrounded by a protective sheath (reference item 108), as seen in figure 14. The sheath is an open-ended tubular member comprising perforations (reference item 110) along at least one section. Furthermore, the perforations are along a generally substantial portion of the tubular member's length. The open-ended, perforated sheath is provided to allow access to the fluid carrier (column 10, lines 29-31). Furthermore, as seen in figure 2, Pawliszyn teaches that is well known to develop a SPME device wherein a fiber (reference item 6) and protective sheath are extracted or retained in a pointed needle (reference item 18). Retaining the protective sheath and the fiber with its adsorbed analytes in



the needle ensures that the sheath is not damaged and the analytes are not disturbed or lost during movement to an analysis device such as a gas chromatograph.

Modifying the teachings of Koehler *et al.* so that the metal sheath comprises an active media coating in lieu of the use of a fiber, as taught by Berg, would allow the device to eliminate the extremely fragile fiber. Furthermore, modifying the teachings of Berg to provide a sheath with perforations along at least a portion of its length, as taught by Pawliszyn, would allow the increased circulation of the material onto the media in order to increase adsorption amount and/or decrease adsorption time.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Koehler *et al.* with the teachings of Berg and Pawliszyn to obtain a sheath for SPME where the sheath is provided with an active media coating on its inner surface, where the sheath is provided with holes in order to increase the amount of sample that the active media is exposed to, and where the sheath is extracted into the needle.

13. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koehler *et al.* in view of Berg and Pawliszyn as applied to claims 1 and 10 above, and further in view of GB 2185265 to Lersmacher.

Koehler *et al.* in view of Berg and Pawliszyn teaches the use of an active media for SPME. In particular, Koehler *et al.* teaches the use of active coating on a fiber comprised of solid polymeric materials such as

polydimethylsiloxane (PDMS)	octadecyltrichlorosilane
polyacrylate	polymethylvinylchlorosilane
graphite	liquid crystalline polyacrylates
carbowax	grafted self-assembled monolayers
silicone	inorganic coatings
polyimide	

and combination of the aforementioned coatings. In the above list graphite is a well-known particulate material. Berg teaches the use of PDMS coating on the inner surface of the sheath.

The use of the specific method of cold-pressing the particulate coating in the manufacture the SPME needle is well known. In order for the particulate material to assume a generally homogenous structure one can use several techniques such as cold pressing, hot pressing, and sintering. All three techniques allow a granular material to be transformed into an essential solid material. Hot pressing and sintering require the use of very high temperatures that may affect the structure of the needle upon which the coating is applied. Furthermore, hot pressing and sintering may drastically alter the grain structure of the particulate material such that it might not perform as well as an analyte trap for SPME. Other techniques such as bonding the particulate material using binding agents would not be preferred as these may affect the materials ability to function as a particulate trap for the analytes in a sample. Therefore, cold pressing would have been an obvious choice to form the particulate material on the inner surface since the transformed material

becomes essentially solid, but it retains the necessary grain structure to perform as an analyte trap in SPME. See also Lersmacher where graphite is cold-pressed to form an adsorption surface.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Koehler *et al.* in view of Berg and Pawliszyn with the teachings of Lersmacher to provide a cold-pressed active coating on the inner surface of a sheath for performing SPME.

***Allowable Subject Matter***

14. Claims 18 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 22-35 are allowed subject to the double-patenting objection noted above.


16. The following is a statement of reasons for the indication of allowable subject matter.

The prior art, such as that taught by Berg, does not teach or suggest the use of an active extraction media being of loose particulate composition.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 26, 2004

  
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